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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,635	05/18/2000	OLIVIER BALLEVRE	P00.0164	7617

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/508,635	Ballevre
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Apr 15, 2002* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *30-41* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [ ] Claim(s) _____ is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [X] Claims *30-41* are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)	4) [ ] Interview Summary (PTO-413) Paper No(s).
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) [ ] Notice of Informal Patent Application (PTO-152)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) [ ] Other:

Pursuant to the directives of paper No. 17 (filed 4/15/02), claims 11-22 have been cancelled, and claims 30-41 added.

Applicants' arguments filed 4/15/02 are acknowledged herewith. A response thereto will be forthcoming after applicants have elected an invention for examination.

*

The amendment filed 4/15/02 is not fully responsive to the previous Office action. In the previous Office action, affirmation of a verbal election to a restriction was required. The restriction in question was the following:

III. Claims 11-13, 15-29, drawn to a method of promoting the growth or recovery of a specific organ in a mammal.

IV. Claim 14, drawn to a method of increasing protein synthesis.

This restriction set forth a distinction between those processes in which a determination of protein synthesis was required, and those which do not. Accordingly, applicants are viewed as non-responsive to the previous Office action. However, in view of the new claims, a new restriction is imposed.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

V. Claims 30-35, 39-41, drawn to a method of promoting growth or recovery of an organ, with the proviso that there is no requirement to affect skeletal muscle one way or another.

VI. Claims 30, 31, 36-41, drawn to a method of promoting growth or recovery of skeletal muscle.

The claimed inventions are distinct.

First, skeletal muscle is not an organ, it is a tissue. In addition, the mass of skeletal muscle can vary considerably from one month to the next in a given human, depending on various factors, but principally the amount of excercise undertaken. Furthermore, there are significant numbers of people who aspire to achieve greater muscle mass even when healthy, whereas there is little motivation among healthy persons to increase the mass of the duodenum. Thus, both the methods of, and motivation for increasing organ weight differ between skeletal muscle and the other organs.

A new restriction at this juncture is justified, since in previous renditions of the claims, no assay method was required. The claims were drawn simply to a method of promoting growth or recovery of an organ. Now, the claims mandate that a specific assay method be conducted. As such, the claims are now something of a hybrid between two distinct methods. In addition, the claims were previously drawn to a method of promoting growth or recovery of an organ. Since skeletal muscle is a tissue, not an organ, the scope has now

been expanded.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

*

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Regardless of which group is selected for examination, the following two elections are required:

(a) the method is drawn to promoting **growth** of the organ, or the method is drawn to promoting **recovery** of the organ, e.g., from a disease or surgery or injury.

(b) the method requires a determination of one of the following "measurable indicators":

a determination of the weight of the organ;

a determination of the protein concentration;

a determination of the RNA concentration;

a determination of the protein synthesis rate and/or daily protein synthesis;

a determination of the protein synthesis capacity;

a determination of the "ribosomal activity".

In addition, if Group V is selected for examination, election of a specific organ is required (e.g., jejunum).

In addition, applicants previous election of protein hydrolyzates remains in force.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention. Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The "371" status of the application is acknowledged. However, a restriction may be imposed if the claimed invention fails to "define a contribution" over the prior art.

MPEP 1850

PCT Rule 13.2, as it was modified effective 01 July 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Independent and Dependent Claims.
Unity of invention has to be considered in the first place only in relation to the independent claims in an international application

and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

As it happens, there is a significant body of literature on the use of protein hydrolyzates to promote growth of skeletal muscle. It is also asserted that references exist which disclose that, in certain physiological situations, the weight of organs (skeletal muscle is not an organ) can be increased by administering protein hydrolyzates to mammals. Accordingly, the claimed invention does not "define a contribution" over the art, and so a restriction is justified.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600